

REMARKS

Reconsideration is respectfully requested in light of the forgoing amendments and the following remarks.

Claims 27-31, 33 and 37-49 are pending. Claims 1-26 and claims 34-36 are directed to a nonelected invention and have been withdrawn from consideration by the Examiner pursuant to Rule 142(b). Newly submitted dependent claims 37-49 are directed to subject matter that corresponds to original claims 8-11 and 15-24, written in a form consistent with the claims that have previously received an action on their merits.

The Section 112 Rejections

Claims 27-31 and 33 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse.

The claims have been amended to address the Examiner's concerns. In light of these amendments, withdrawal of the rejection is respectfully requested.

Additionally, Examiner's concerns under 37 CFR 1.75(c) relating to claims 32 and 37 have been addressed by the amendments above.

The Examiner argues that two phases in the claims are unclear. The Examiner should be aware that the specification is addressed to a person skilled in the art. It is our intention that the phraseology used in these claims would be clear to a person skilled in the art, and such a skilled artisan would know not only what these terms mean, but would also be able to deduce therefrom the metes and bounds of the claim.

The Examiner asks how one assures that the solvent access is necessarily "via the pores." The granules are treated with a solvent in order to extract the desired compound from the intact cells inside the granules. This may be achieved by immersing the granules in a solvent, or by placing the granules on a bed and then passing a solvent thereover. Although the outer surface of the granules will therefore come into contact with the solvent, it is the pores that significantly increase the surface area and therefore allow greater access of the solvent to all the dead fungal cells within the granules. Indeed, the solvent gains access to the interior of the granules by entering through the pores. Clearly the pores need to be large enough to allow the solvent to

enter, and for the solvent to then leave those pores after having extracted and then dissolved the desired compound. It is of course implicit that if the structure allows a solvent access via the pores, then the physical dimensions of the pores are such to allow entry and exit of the solvent. The pores thus allow solvent to contact the cells inside the pores (a "structure having pores," and "porous," are synonymous). The word "pore" can be found in dictionaries and means an opening, orifice, hole or outlet. The pores thus allow access to the cells inside the granules either for a solvent or even to allow escape of air and water (see the discussion concerning drying on page 18, lines 16-18).

"Desired" has been deleted to advance prosecution. However, applicants urge that the term does not render the claims indefinite. A "desired" compound is a compound that one wishes to extract. This, it is supposed, is opposite from an "undesired" compound, which one may not want to extract from the granules. Admittedly, it is a subjective term, but it would be understood by a person skilled in the art that a desired compound is one that one wishes to obtain, rather than an unwanted compound which might be thought of as being an impurity. There is no correlation between the fungus, the solvent and the class of compound because the invention can be used to extract many different compounds, and of course the nature of the compound will determine what solvent one employs. The type of microorganism will of course be one which has produced the compound that it is desired to extract.

Withdrawal of the rejection is respectfully requested in light of the amendments and comments above.

The Art Rejections

Claims 27, 29, 30-32, and 37 are rejected under 35 USC 102 (e), as anticipated by Rhodes *et al.* (U.S. Patent No. 5,759,562). Applicants respectfully traverse.

The claims now employ partially closed "consisting essentially of" terminology that clearly distinguishes over the teachings of Rhodes *et al.*

Rhodes *et al.* teaches a composition containing an insecticidal amount of blastophores and a complex nutrient source for application to soil to control soil dwelling insect pests. A blastophore is a spore produced by a budding process along the mycelium or by a single spore. A spore is a resistant body formed by certain microorganisms, a resistant resting cell; a primitive

unicellular reproductive body. Spores are not the materials from which one readily extracts “commercial” amounts of intracellular compounds, e.g. β -carotene, Vitamin B-12, etc.

A spore and nutrient composition teaching is simply not a teaching of a granulated intact fungal cells having a porous structure which facilitates the extraction of intracellular compounds. The microbial cells are dead (killed).

Additionally, claim 27 specifies that the granules are porous and/or have hollow channels. These pores and channels provide access into the center of the granules (see page 20, starting at line 11 and continuing to the first five lines of page 21). Further, the granules are free flowing (see page 19, line 28 and page 20 at line 4). As already noted, “consisting essentially of” further excludes the Rhodes *et al.* compositions that are directed to live cells. Please also note that the dried granules have a porous structure that allows access for the solvent to the dead cells to extract a desired compound therefrom. Basis for this can be found in the paragraphs spanning pages 6 and 7, on page 14 (first four lines) and on page 20 at line 31.

Withdrawal of the rejection is respectfully requested.

Claims 28-33 and 30-40 are rejected under 35 USC 102(b) as anticipated by or, in the alternative, under section 103(a), as obvious over Huang *et al.* or Cockram *et al.* Applicants respectfully traverse.

The three independent claims, as amended, specify that the structure of the granulate and dry granules allow, via the pores and/or channels, access of a solvent to the dead cells so that one can isolate or extract the “desired” compound therefrom. The same is true of the granular particles of claim 29, although they require drying first (to give the dry granules).

Further, the present application teaches numerous advantages of granulation techniques in order to efficiently permit extraction of desired compounds from biomass or fungal cell materials. The benefits are illustrated in the Examples, Tables and Figures. In particular, consider Tables 2 and 5; Example 25 in contrast to Comparative Example 26; and Figures 5 and 6; Table 5, Example 25 in contrast to Comparative Example 26. These comparisons illustrate the benefits of the granulated/extruded biomass. Table 2 illustrates the effects of different dry matter contents on the quality of the extrudate. Figures 5 and 6 illustrate the enhanced porosity of the claimed product.

According to the practice of the present invention, granular particles are formed from biomass having a dry matter content from 25 to 80%. Following drying of the particles, desired

compounds are extracted therefrom. Granular particle size, water content of the biomass and its control at various stages of the process are critical to achieving the claimed granular structures which possess numerous advantages. The resultant dried granules permit maximum solvent access for extraction while at the same time avoiding fines or dust from milling that may impede filtration. Granules permit more efficient extractions than larger particles such as flakes. (See the Specification at page 4, lines 6-32; page 7, line 6; page 13, lines 29-32; page 20, lines 33-36.) Further, damage to fungal cells is minimized when granule formulations are prepared, such as by extrusion, and there is generally no need to disrupt cells prior to extraction of desired compounds. (See page 5, lines 7-9; page 6, lines 10-17; page 14, lines 8-11; page 21, line 7; page 7, line 10.) This permits the granular biomass to be storage-stable which allows "breaks" in processing, e.g., drying of the extruded granules does not have to be immediately undertaken after their preparation.

None of these advantages (or other advantages referred to in the Specification) are at all evident from Huang *et al.* or Cockram *et al.*, alone or in combination.

In addition, extraction of an intracellular component in good yield is clearly taught in the specification.

The newly cited Cockram *et al.* reference deals with the texturizing of a mycelium fungal mass containing 20% to 35% solids in a water base. There is no drying step mentioned. A solvent-extracted compound is not mentioned either. The process described does not produce granules. Rather, it forms strands from filaments containing mycelium mass. The strands are incorporated into a food stuff. There is clearly no disclosure of the need to enhance porosity of fungal cells or how to do it.

Dealing first with the Cockram *et al.* document, this refers to texturizing a mycelial fungal mass by extruding fungi through a die under high pressure (column 2, lines 24-25). This forms axially parallel filaments (column 2, lines 66-67). These are not granules. In addition, there is no disclosure that the fungal cells must be dead as required by the claims. The process of this document could easily be conducted on live cells. There is nothing in the Cockram *et al.* document that teaches that the composition is either free flowing or is granular.

Huang is directed to the treatment of a proteinaceous mass of fungal fibers by rapid dielectric heating in order to reduce the amount of nucleic acid therein. The end product is one that has the texture and chewability of meat. This is not akin to the extraction of Vitamin B-12.

The Applicants note the Examiner's comments about the U.S. Patent and Trademark Office not being equipped to manufacture products by prior art methods and then to compare those with the products now claimed. However, before Applicants should be required to undertake the expense of a side-by-side comparison, the products should reasonably appear to be the same. That is not the case here. The different purpose(s) of the prior art suggest preparation and product differences from that claimed herein. The presence of inherent characteristics must be certain and not based on mere speculation.

Neither document specifically discloses granules that have a structure that allows a solvent access, via the pores, to the dead cells in order to isolate or extract desired compounds therefrom. Both of these documents deal with texturizing fungi, in particular to produce filamentous products or fibre bundles. There is no intention to extract a compound from these elongate extrudates. There is therefore no reason to suppose that they have a structure that allows solvent access. Indeed, neither of them discloses that the products are porous, nor that the structure of the pores allows solvent access to the dead cells.

The Examiner has not specified where in either of these two documents all of the features of the claims can be found. Instead, the Examiner is merely speculating that as both documents refer to extrusion of a fungal biomass then one must obtain the same product as now presently claimed. That is not true, and it is a false assumption to make. The Examiner has no evidence that the prior art products would have the same feature as the granules of the present application, especially as they have different uses and purposes, and therefore neither document can be considered to be novelty destroying.

Further, the specification in the passages referred to above illustrate benefits for the claimed invention that are not expected from the cited references.

It is also submitted that both of the cited documents are entirely in different fields, and while they all refer to fungal biomass, there the commonality ends: the uses of the biomass are very different.

The problem that a skilled artisan faces in the present application is to efficiently extract a desired compound from a biomass. The disclosed invention achieves this by extruding the (already killed) intact cells into a granular form which is porous and has hollow channels. These pores and channels allow access of the solvent to the dead intact fungal cells and because a large

surface area is provided to the solvent, the desired compound can be extracted from those cells with great efficiency. None of the prior art documents extrude, or form granulates.

It is not seen why the Cockram and Huang processes, which are clearly in different fields of endeavor and have different ends in mind than that of the invention, would reasonably be expected to result in a product having the claimed characteristics.

For a start, both of these documents intend to produce textured fungal products for human consumption. These substances are incorporated into a foodstuff. In contrast, the granules of the present application are not intended to be edible; instead, they are to be treated with a solvent in order to isolate a compound therefrom. That places a very different emphasis on the different products and their uses.

The art produces parallel filaments or mycelial fibers; in the case of Cockram *et al.*, the products remain fibrous (they are not granular). This is to provide fibrous texture. In contrast, the granules of the present application (which are not fibre bundles) possess pores to allow access of solvent for compound extraction. Indeed, even after the parallel filaments are formed, further extrusion forms the filaments into strands (column 3, lines 10-11) so at all times there are continuous threads or filaments rather than granules.

While the Examiner may have concerns that the products of the prior art might be similar to those claimed, it is clear from the very different uses that it is likely, beyond reasonable doubt, that the granules of the present application have a different structure from those described in the prior art.

Since neither a proper *prima facie* case of anticipation or obviousness has been established in regard to the claims as amended; and further, since the results achieved by the claimed invention would not be expected from the applied prior art, withdrawal of the rejection is respectfully requested.

CONCLUSION

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this

document to **Deposit Account No. 03-1952** referencing docket no. 251502006900. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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